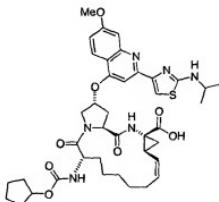


CLAIMS

We Claim:

- 1) An oral pharmaceutical composition comprising about 25 mg to 500 mg of the
5 following Compound (1) or a pharmaceutically acceptable salt thereof:



(1)

10 dissolved in at least one solvent selected from polyethylene glycol , ethanol, propylene glycol and water, and mixtures thereof.

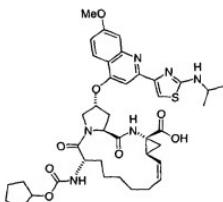
2) An oral pharmaceutical composition according to claim 1, wherein said composition comprises about 25 mg to 500 mg of Compound (1) or a pharmaceutically acceptable salt thereof, dissolved in a mixture of a polyethylene glycol and ethanol.

- 15 3) A kit comprising:
20 (a) about 25 mg to 500 mg of Compound (1), or a pharmaceutically acceptable salt thereof; and

(b) at least one of the following additional agents: an antiviral agent, an immunomodulatory agent, another inhibitor of HCV NS3 protease, an inhibitor of another target in the HCV life cycle, an HIV inhibitor, an HAV inhibitor, an HBV inhibitor or a liver immunoprotective agent.

4) A method of treating or preventing HCV infection in a mammal comprising administering to said mammal about 50mg to 1000mg of the following Compound (1), or a pharmaceutically acceptable salt thereof, per day in single or multiple doses:

5



(1)

10 5) A method according to claim 4, wherein about 50 mg to 300 mg of Compound (1) or a pharmaceutically acceptable salt thereof, is administered to said mammal per day.

6) A method according to claim 4, wherein about 300 mg to 500 mg of Compound (1) or a pharmaceutically acceptable salt thereof, is administered to said mammal per day.

15

7) A method according to claim 4, wherein about 500 to 1000 mg of Compound (1) or a pharmaceutically acceptable salt thereof, is administered to said mammal per day.

8) A method according to claim 4, wherein the HCV is of the genotype 1 variety.

20

9) A method according to claim 4, wherein the HCV is chronic HCV of the genotype 1 variety.

10) A method according to claim 4, wherein at 48 hours after the first administration of
25 Compound (1) or a pharmaceutically acceptable salt thereof to the mammal, the viral load

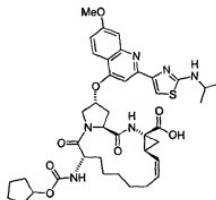
of HCV in the mammal is at least 1 log lower than the viral load of HCV in the mammal when Compound (1) is first administered to said mammal.

- 11) A method according to claim 4, wherein at 48 hours after the first administration of
5 Compound (1) or a pharmaceutically acceptable salt thereof, to the mammal, the viral load of HCV in the mammal is at least 2 log lower than the viral load of HCV in the mammal when Compound (1) is first administered to said mammal.
- 12) A method according to claim 4, wherein at 48 hours after the first administration of
10 Compound (1) or a pharmaceutically acceptable salt thereof, to the mammal, the viral load of HCV in the mammal is at least 3 log lower than the viral load of HCV in the mammal when Compound (1) is first administered to said mammal.
- 13) A method according to claim 4, wherein said mammal is a human, wherein about
15 50 to 1000 mg of Compound (1) is administered to said human per day, wherein the HCV infection is chronic HCV infection of the genotype 1 variety, and wherein at 48 hours after the first administration of Compound (1) to the mammal, the viral load of HCV in the mammal is at least 1 log lower than the viral load of HCV in the mammal when Compound (1) is first administered to said mammal.
- 20
- 14) A method according to claim 13, wherein at 48 hours after the first administration of Compound (1) to the mammal, the viral load of HCV in the mammal is at least 2 log lower than the viral load of HCV in the mammal when Compound (1) is first administered to said mammal.
- 25
- 15) A method according to claim 13, wherein at 48 hours after the first administration of Compound (1) to the mammal, the viral load of HCV in the mammal is at least 3 log lower than the viral load of HCV in the mammal when Compound (1) is first administered to said mammal.

- 16) A method according to claim 13, wherein about 300 to 500 mg of Compound (1) is administered to said human per day.
- 17) A method according to claim 14, wherein about 300 to 500 mg of Compound (1) is
5 administered to said human per day.
- 18) A method according to claim 15, wherein about 300 to 500 mg of Compound (1) is administered to said human per day.
- 10 19) A method according to claim 13, wherein about 400 mg of Compound (1) is administered to said human per day.
- 20 20) A method according to claim 14, wherein about 400 mg of Compound (1) is administered to said human per day.
15
- 21) A method according to claim 15, wherein about 400 mg of Compound (1) is administered to said human per day.
- 22) A method according to claim 4, wherein Compound (1), or a pharmaceutically acceptable salt thereof, is administered by an oral pharmaceutical composition comprising Compound (1), or a pharmaceutically acceptable salt thereof, and at least one pharmaceutically acceptable carrier or diluent.
20
- 23) A method according to claim 22, wherein Compound (1) or a pharmaceutically acceptable salt thereof is administered by an oral pharmaceutical composition comprising Compound (1), or a pharmaceutically acceptable salt thereof, dissolved in at least one solvent selected from polyethylene glycol, ethanol, propylene glycol, water and mixtures thereof.
25
- 30 24) A method according to claim 23, wherein the solvent is a mixture of polyethylene glycol and ethanol.

- 25) A method according to claim 22, wherein said composition further comprises at least one agent selected from: an antiviral agent, an immunomodulatory agent, another inhibitor of an HCV NS3 protease, an inhibitor of another target in the HCV life cycle, an HIV inhibitor, an HAV inhibitor, an HBV inhibitor and a liver immunoprotective agent.
- 5
- 26) A method according to claim 4, wherein the Compound (1), or a pharmaceutically acceptable salt thereof, is co-administered with a least one additional agent selected from: an antiviral agent, an immunomodulatory agent, another inhibitor of an HCV NS3 protease, an inhibitor of another target in the HCV life cycle, an HIV inhibitor, an HAV inhibitor, an HBV inhibitor and a liver immunoprotective agent, and said additional agent is administered to the patient prior to, concurrently with, or following the administration of Compound (1), or a pharmaceutically acceptable salt thereof.
- 10
- 15) 27) A method for validating an assay useful for determining whether one or more substances, alone or in combination, inhibit(s) the replication of HCV, comprising: a) running a control substance in said assay, wherein the control substance comprises the following Compound (1), or a pharmaceutically acceptable salt thereof, and b) determining the HCV replication inhibitory activity of said control substance in the assay:

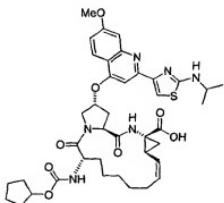
20



(1).

- 28) A method for determining the relative effectiveness of one or more substances, alone or in combination, to inhibit the replication of HCV, comprising: a) running said
- 25

substance(s) in an assay that is useful for determining whether a substance inhibits the replication of HCV; b) determining the HCV replication inhibitory activity of said substance(s) in said assay; and c) comparing said HCV replication inhibitory activity to the HCV replication inhibitory activity of a control substance that is determined in an identical 5 or different assay, wherein the control substance comprises the following Compound (I) or a pharmaceutically acceptable salt thereof:



(I).